

REMARKS

I. Claim Status

Claims 24-30 and 33-51 are pending, with claims 26, 27, 36-39, 41, 43-45, 49, and 50 withdrawn from consideration, claims 25, 25, 29, and 46 allowed, and claims 28, 29, 30, 33-35, 40, 42, 44, 48, and 51 under examination. Applicants have amended paragraph "(iv)" of claim 28 to recite, "a sequence of at least 30 consecutive amino acids that includes amino acid position 122 of SEQ ID NO:12 and is found within positions 93-151 of SEQ ID NO:12." The specification supports this amendment at, for example, page 12, line 36, and page 13. Thus, this amendment to claim 28 does not introduce new matter.

Applicants have also added new claims 52-55, which derive from the specification as filed at, for example, page 13, lines 5-19, and page 14, lines 24-37. Thus, none of the new claims adds new matter.

Applicants acknowledge with appreciation the Office's withdrawal of (i) the prior objection to claim 28 due to informalities; (ii) the rejection of claims 28, 30, 33-35, 40, and 42 under 35 U.S.C. 112, second paragraph; (iii) the written description rejection of claims 25, 27, 40, and 42; (iv) the enablement rejection of claims 24, 26, 33-35, 40, and 42; and the prior anticipation rejection of claims 28, 33-35, and 40 based on Langley *et al.* (EP 0533492) and of claim 28 based on GenPept BAC17521. The Office now (i) objected to the specification and proposed an amendment; (ii) withdrew certain claims for allegedly reading on non-elected species; (iii) introduced new anticipation and obviousness rejections based on two new references, namely GenBank AAO41333 and GenBank AAF36498; rejected claims 47 and 48 as allegedly being substantial

duplicates of claims 25 and 26, respectively. Applicants address each of these actions below.

II. Election/Restrictions

The Office withdrew from consideration claims 26, 27, 43-45, 49, and 50 allegedly because they read on non-elected species. Office Action, page 2. Applicants respectfully traverse. According to the Office:

In the submission of August 11, 2009, the Applicant elected a species of the invention comprising amino acid of position 73 of SEQ ID NO: 12 (position 115 of HBV variant HDB 05). The Applicant determined not to be elected a combination of such positions. Thus, combinations of the various positions are presently considered non-elected species until such time as the elected species is found allowable or cancelled.

As amended or presented, claims 27, 43-45, and 50 read on such non-elected species, and are therefore withdrawn from consideration.

Office Action, page 2. The Office also added that “in view of the amendments to the claims, examination has been extended to additional species of the claimed inventive group.” *Id.* Applicants thank the Examiner for extending examination to additional species.

The Office has taken the position that the elected species is directed to peptides containing only one of the 5 variant positions—Arg 73 (position 115 of HBV variant HDB 05)—and not to peptides containing more than one of the 5 variant positions (namely, more than one of the substitutions of HBV variant HDB05 positions T 115 (R), P 120 (Q), S 154 (L), E 164 (V), and Q 181 (R)). Hence, the Office has withdrawn claims 26, 27, 43-45, 49, and 50 from consideration, all of which contain language directed to peptides containing multiples of the 5 variant positions. On the other hand, the Office has already deemed claim 24 allowable. Claim 24 is a generic claim and

claims 26, 27, 43-45, 49, and 50 are all species of the genus of claim 24 because (i) claim 24 requires no material element in addition to those required by the species claims, and (ii) the species claims 26, 27, 43-45, 49, and 50 each require all of the limitations of claim 24. See MPEP § 806.04(d).

Specifically, claim 24 recites a peptide comprising “at least one of the five amino acid substitutions.” (emphasis added). The same possible substitutions are recited in claims 26, 27, 43-45, 49 and 50. A peptide that has “at least two,” “at least three,” “at least four,” or all of “the five substitutions,” as recited in claims 26, 27, 43-45, 49, and 50, necessarily has to have “at least one” of the substitutions recited in claim 24. Under 37 CFR § 1.141, MPEP 806.04(a), and MPEP 821.04(a), because the species claimed in claims 26, 27, 43-45, 49, and 50 include all the limitations of the generic claim 24, these claims should be rejoined as a reasonable number of species of generic claim 24. Moreover, because the Office already determined the genus of claim 24 to be patentable over the prior art, all species of this genus are necessarily also patentable over the prior art. Consequently, Applicants respectfully request that the Office rejoin and allow claims 26, 27, 43-45, 49, and 50 in this application.

III. Objections to the Specification and Requested Amendment to the Specification

The Office objected to the specification as allegedly failing to provide proper antecedent basis for the claimed subject matter. Office Action, page 3. Specifically, the Office concedes that the specification provides written description support for the limitations of claim 28, but suggests that the language of claim 28 be recited in the specification. Per the Office’s suggestion, Applicants have amended the specification to insert the language of claim 28 (as currently amended) on page 13.

IV. Rejections Under 35 U.S.C. § 102(a)

The Office newly rejected claims 28, 30, 33, 40, and 51 under 35 U.S.C. § 102(a) as allegedly being anticipated by GenBank AAO41333. The Office added that the GenBank AAO41333 "reference has a publication date after the foreign priority date claimed by the present application," but Applicants could not heretofore rely upon the foreign priority date to overcome this rejection because a translation of the foreign priority application has not been made of record. Office Action, page 6. In accordance with 37 CFR 1.55, Applicants now submit herewith a certified English translation of German Priority Application No. 103 28 080.4, filed June 20, 2003 (the same day that GenBank AAO41333 was published). The rejected claims are supported in the German Priority document by at least Figure 6 (with sequence positions provided relative to HDB05) and page 15, lines 22-29. Accordingly, Applicants submit that this rejection is now moot and respectfully request its withdrawal.

V. Rejections Under 35 U.S.C. § 102(b)

The Office newly rejected claims 28, 30, 33, 40, and 51 under 35 U.S.C. § 102(b) as allegedly being anticipated by GenBank AAF36498. According to the Office, the fragment comprising at least 6 amino acids found within residues 117-127 of SEQ ID NO:12 and comprising the amino acid at position 122 of SEQ ID: 12 (V122) is found in residues 323-333 of the sequence disclosed in GenBank AAF36498. Office Action, page 6. Applicant respectfully traverses this rejection. This rejection is now moot due to the amendment to claim 28, from which claims 30, 33, 40, and 51 depend.

As amended, claim 28 now recites, in relevant part (emphasis added):

(iv) a sequence of at least 6 30 consecutive amino acids that includes amino acid position 122 of SEQ ID NO:12 and is found within positions ~~117-127~~ 93-151 of SEQ ID NO:12.

Any fragment of SEQ ID NO:12 consisting of a sequence of at least 30 consecutive amino acids from SEQ ID NO:12 that includes the Val at amino acid position 122 must also include either the Leu at position 112 or the Arg at position 139 (all these positions numbered per the numbering in SEQ ID NO:12). Because GenBank AAF36498's sequence contains a Ser and a Gln at each of those relative positions, respectively, GenBank AAF36498's sequence does not anticipate claim 28 nor its dependent claims 30, 33, 40, and 51. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b), as well as allowance of claims 28, 30, 33, 40, and 51.

VI. Rejections Under 35 U.S.C. § 103(a)

The Office newly rejected claims 34, 35, and 42 as allegedly obvious over either GenBank AAO41333 or GenBank AAF36498 as applied in the anticipatory section discussed above, and further in view of U.S. Patent No. 5,856,084 (the '084 patent). Office Action, page 6. Applicants respectfully traverse.

According to the Office, the cited Genbank references teach the claimed peptides but do not teach the claimed methods. Office Action, page 7. Specifically, the claimed methods are directed to (i) the preparation of the claimed peptides (claims 34 and 35) and (ii) identifying antibodies directed against a hepatitis B antigen (claim 42) and the Office acknowledges that none of the Genbank references teach these methods. *Id.* However, the Office alleges that the '084 patent remedies these two deficiencies in the cited Genbank references as follows. First, because the '084 patent allegedly teaches that HBV antigens may be recombinantly expressed through the methods of claims 34 and 35, according to the Office, it allegedly remedies the above deficiency with respect to these claims. Second, because the '084 patent allegedly teaches that HBV S and

pre-S antigens are useful in immunoassays, including assays for the detection of anti-HBV antibodies, the Office argues that it allegedly remedies the above deficiency with respect to claim 42.

Applicants submit that the submission of a certified copy of the English translation of the priority document German Application No. 103 28 080.4 together with the proposed amendments to claim 28, from which claims 34, 35, and 42 depend, render the Office's arguments moot. First, because GenBank AAO41333 no longer is prior art, it can no longer teach the claimed peptides for purposes of the obviousness analysis. Second, because GenBank AAF36498 does not teach the peptides of amended claim 28, which as amended requires "(iv) a sequence of at least 30 consecutive amino acids that includes amino acid position 122 of SEQ ID NO:12 and is found within positions 93-151 of SEQ ID NO:12," GenBank AAF36498 can no longer teach the peptides of dependent claims 34, 35, and 42. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b), and the timely allowance of claims 34, 35, and 42.

VII. Double Patenting Objection under 37 CFR 1.75

The Office objected to claims 47 and 48 as allegedly being substantial duplicates, respectively, of claim 25 and 46. Office Action, page 7. Applicants have canceled claims 47 and 48, thereby rendering this objection moot.

VIII. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 11, 2010

By: Rebecca M. McNeill
Rebecca M. McNeill
Reg. No. 43,796
(202) 408-4086